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CITIZEN PETITION

The Council on Radionuclides and Radiopharmaceuticals ("CORAR"), an association of 17 companies that manufacture and distribute radiopharmaceuticals, sealed sources, and radionuclides primarily for use in medicine and life science research, submits this Citizen Petition ("Petition") under 21 C.F.R. § 10.30, requesting that the Food and Drug Administration ("FDA" or "the Agency") determine that sponsors of "human drug applications" for positron emission tomography ("PET") drugs be exempt from paying certain user fees assessed pursuant to the Prescription Drug User Fee Act of 1992, as amended ("PDUFA").[1] CORAR is concerned that, because of the unique characteristics and properties of PET drugs, the assessment of establishment user fees unfairly burdens commercial PET drug manufacturers. Relief from this burden will become particularly important once FDA requires the submission of marketing applications for PET drugs.

[1] Pub. L. No. 102-571, 106 Stat. 4491 (1992).

2005P-0358

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I. ACTION REQUESTED

CORAR requests that FDA establish a class waiver under which manufacturers of PET drugs are exempt from multiple establishment user fees, and are subject, at most, to a single establishment fee for each approved "human drug application."

II. STATEMENT OF GROUNDS

A. Background

1. PET Drugs and their Historical and Emerging Regulatory Schemes

PET drugs are produced by tagging (i.e., "labeling") a substrate compound with a positron emitting isotope, which is produced in cyclotrons (i.e., devices that accelerate protons or deuterons to the high energies needed for a nuclear reaction to occur). Once injected, the isotope travels through a patient's bloodstream and is distributed in certain tissues. Using a PET camera, nuclear physicians measure the different rates at which the isotope emits positrons, based, for example, on the different ways in which different types of tissue metabolize the drug's substrate, and thereby produce computerized images of biochemical processes and tissue structures within the body. Physicians use the resulting images to diagnose, stage, and monitor diseases (e.g., focal epilepsy, certain cardiac diseases, dementias, and lung, breast, prostate, and colorectal cancer).

Because the radioactive half-lives of positron-emitting isotopes used in PET drugs are short (e.g., from several minutes to a few hours),[2] the drugs must be used soon after they are prepared. Accordingly, PET drugs are prepared by PET drug facilities only as needed and in close proximity to the medical facilities where they are used. Their necessarily decentralized and relatively small-scale preparation distinguishes PET drugs from other diagnostic and therapeutic drugs, which typically have long shelf-lives and therefore can be manufactured at centralized facilities and distributed over long distances for commercial use.

Until recently, FDA generally did not regulate providers of PET drugs as conventional pharmaceutical manufacturers, but instead considered the preparation of PET drugs for dispensing under a prescription to fall within the practice of pharmacy. By extension, PET drug providers, like other pharmacies engaged in drug compounding, were not required to comply with the

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[2] For example, one of the most commonly used PET agents, Fludeoxyglucose (FDG) F 18 Injection, has a half-life of 109.7 minutes.

regulatory requirements imposed on conventional drug manufacturers. PET drug providers, for example, have not had to obtain FDA approval of a marketing application before marketing their drugs, register their facilities as drug establishments, or comply with current Good Manufacturing Practices ("cGMPs").

In the early 1990s, as PET drug production expanded, FDA became increasingly convinced of the need for heightened regulation of PET drugs. FDA announced in 1995 that it would henceforth regulate PET drugs as "new drugs" subject to the New Drug Application ("NDA") requirements of the Federal Food, Drug, and Cosmetic Act ("FDC Act").[3] FDA's initiative to change its regulatory approach to PET drugs was superceded by amendments to the FDC Act contained in the FDA Modernization Act of 1997 ("FDAMA"). These amendments placed a moratorium on FDA's regulation of PET products as "new drugs" until FDA establishes procedures by which PET drugs are to be approved under the FDC Act's new drug approval process, and establishes appropriate PET drug cGMPs.[4] During this moratorium, FDA has encouraged PET centers to voluntarily submit marketing applications for approval.[5]

FDA has engaged in an extensive dialogue with the PET drug industry since the enactment of FDAMA regarding the emerging regulatory regime. For example, the Agency has issued draft guidances and draft cGMP regulations for comment, and has conducted several public meetings to discuss these and other issues.[6]

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3 See FDA, Notice, Regulation of Position Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop, 60 Fed. Reg. 10,594, 10,595 (Feb. 27, 1995).

4 See FDAMA § 121. Section 121 of FDAMA also instructs FDA to consult with the PET drug industry during its deliberations, and sets forth deadlines by which PET drug producers must comply with FDA's new approval procedures and cGMPs. Id.

5 For example, in March 2000, FDA published a draft guidance document on the format and content of PET drug marketing applications. See FDA, Draft Guidance for Industry, PET Drug Applications — Content and Format for NDAs and ANDAs (Fludeoxyglucose F 18 Injection; Ammonia N 13 Injection; Sodium Fluoride F 18 Injection), available at http://www.fda.gov/cder/guidance/3453dft.pdf, (stating that "[n]othing prohibits the voluntary submission and FDA review of [PET drug] applications" during the moratorium on requiring marketing applications).

6 These draft guidance documents and regulations, public meeting transcripts, and related documents can be found on FDA's PET drug webpage, available at http://www.fda.gov/cder/regulatory/pet/default.htm.

2. *PDUFA User Fees and User Fee Exemptions, Waivers, and Reductions*

Under PDUFA, FDA collects three types of user fees for a drug product that is the subject of a "human drug application:" (1) an application fee; (2) an establishment fee; and (3) a product fee.[7] The term "human drug application" is defined to mean "full" 505(b)(1) NDAs and 505(b)(2) applications for either a new chemical entity or a new "indication for a use" of a previously approved drug product.[8]

The application fee is a one-time fee that must be paid in order for FDA to accept an application for filing. Establishment fees are assessed annually for "each prescription drug establishment listed in [an] approved human drug application as an establishment that manufactures the prescription drug product named in the application."[9] Moreover, "the establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment."[10] Finally, product fees are assessed annually for each prescription drug listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") that is the subject of an approved "human drug application."[11]

The FDC Act provides three mechanisms whereby any firm that submits or has an approved "human drug application" can request the Agency to waive or reduce user fees: (1) the "public health" mechanism; (2) the "barrier to innovation" mechanism; and (3) the "fees-exceed-the-costs"

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7 The PDUFA user fees established for Fiscal Year 2006 are substantial, and are likely to rise in subsequent Fiscal Years. See FDA, Notice, Establishment of Prescription Drug User Fee Rates for Fiscal Year 2006, 70 Fed. Reg. 44,106 (Aug. 1, 2005), available at http://www.fda.gov/OHRMS/DOCKETS/98fr/05-15159.pdf.

8 FDC Act § 735(1).

9 Id. at § 736(a)(2)(A)(ii).

10 Id. at § 736(a)(2)(A)(ii) (emphasis added). The statute further states that "[i]n the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees. . . ." Id. at § 736(a)(2)(A)(ii).

11 See id. at § 736(a)(3)(A).

mechanism.[12] In addition, a firm that qualifies as a "small business" (i.e., 500 or fewer employees, including employees of affiliates) and that has no prescription drug products introduced or delivered for introduction into interstate commerce may request FDA to waive the application fee for its first "human drug application."[13] The first two of these waiver mechanisms are relevant here.

Public health waiver: Section 736(d)(1)(A) of the FDC Act provides that user fees may be waived or reduced if FDA finds that "such waiver or reduction is necessary to protect the public health." The Agency has explained that a "public health" waiver/reduction may be appropriate when: (1) the product protects the public health; and (2) the person requesting the waiver shows that a waiver is necessary to continue an activity that protects the public health.[14]

Barrier to innovation waiver: Section 736(d)(1)(B) of the FDC Act provides that user fees may be waived or reduced if FDA finds that "the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances." The Agency has explained that a "barrier to innovation" waiver/reduction may be appropriate when: (1) the product for which the waiver/reduction is being requested is innovative, or the entity requesting the waiver/reduction is otherwise pursuing innovative drug products or technology; and (2) the fee would be a significant barrier to the entity's ability to develop, manufacture, or market innovative products or technology.[15]

In addition to these criteria, FDA also considers other factors in determining whether either a "public health" or "barrier to innovation" waiver/reduction should be granted. These factors include the size and annual gross revenues of a business, whether a "human drug application" is for a "new chemical entity," or has "priority" review status or "fast track" status, and, for a "barrier to innovation" waiver/reduction, special circumstances subject to FDA's discretion.[16] The Agency has stated that it intends to use the "public health" and "barrier to innovation" waiver/reduction mechanisms primarily to justify a waiver or reduction from establishment fees.[17]

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12 See id. at § 736(d)(1).

13 See id. at § 736(d)(3).

14 See FDA, Interim Guidance Document for Waivers of and Reductions in User Fees, at 13 (July 16, 1993).

15 See id. at 13-14.

16 See id. at 13-14, 16.

17 Id. at 16.

B. Argument

1. PDUFA User Fee Applicability to PET Drugs

Under § 121(c)(2) of FDAMA, FDA may not require the submission of NDAs (or Abbreviated NDAs) for PET drugs until two years after the Agency establishes procedures for marketing application approval and cGMP requirements for PET drugs. FDA has not yet established these procedures and requirements. Notwithstanding the moratorium on requiring marketing applications, FDA has encouraged PET centers to voluntarily submit marketing applications for approval. Voluntarily submitted marketing applications are subject to PDUFA user fees, unless otherwise exempted by the statute or waived/reduced by FDA. Once the moratorium ends and all PET drugs are subject to the premarket approval requirements, and "human drug applications" are submitted, all PET drugs will be subject to the application, establishment, and product fees established for that particular Fiscal Year, as well as be eligible for user fee exceptions and waivers/reductions.

Because of the unusual characteristics of PET drugs, and once all PET drugs are regulated as "new drugs," the assessment of establishment user fees, in particular, will significantly and unfairly burden commercial PET drug manufacturers. Due to the short half-lives of PET drugs, a commercial manufacturer that supplies PET drugs nationally, or even regionally, requires multiple manufacturing establishments located throughout the U.S. or the region (as the case may be). Each of these establishments must be identified in any marketing application submitted to FDA. Because establishment fees are assessed annually for "each prescription drug [manufacturing] establishment listed in [an] approved human drug application," PET drug applicants would be assessed multiple establishment fees.[18] Such multiple fee assessments would be patently unfair, particularly for an industry that will soon be saddled with numerous new and expensive legal and regulatory burdens.

When Congress enacted FDAMA § 121, it instructed FDA to "take account of the special characteristics of [PET] drugs and the special techniques and processes required to produce these drugs" to increase their availability to the patients who need them.[19] CORAR believes that to carry out Congress' instructions and ease the regulatory burden on the PET drug industry, it would be prudent and fair for FDA to determine that "human drug applications" for PET drugs currently approved, and those "human drug applications" that will be approved once NDA submissions are

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[18] FDC Act § 736(a)(2)(A).

[19] FDAMA § 121(c)(1)(A).

required, will, at most, be subject to a single establishment fee. As explained below, there is not only adequate basis in the law for such a determination, but FDA is required to make such a determination to ensure that similarly situated parties are treated equitably. Moreover, the creation of this type of "class waiver" is not unprecedented.

a. PET Drugs Qualify for Either a "Public Health" or "Barrier to Innovation" Waiver

FDA guidance interpreting the "public health" waiver provision of the FDC Act explains that a waiver may be appropriate when: (1) the product protects the public health; and (2) the person requesting the waiver shows that a waiver is necessary to continue an activity that protects the public health.[20] FDA guidance also explains that a "barrier to innovation" waiver may be appropriate when: (1) the product is innovative, or the entity requesting the waiver/reduction is otherwise pursuing innovative drug products or technology; and (2) the fee would be a significant barrier to the entity's ability to develop, manufacture, or market innovative products or technology.[21]

Under the first prong of each waiver mechanism, FDA often makes a determination whether a product protects the public health and/or is innovative. As explained below, as a class, PET drugs both protect the public health and are innovative.

First, it is in the interest of public health not to discourage commercial PET manufacturers from making PET drugs readily available at numerous medical facilities throughout the U.S. The short radioactive half-lives of positron-emitting isotopes necessarily mean that PET drugs must be administered to patients shortly after they are produced. Without PET centers in close proximity to a medical facility, patients would have to travel, in some cases, hundreds of miles to the nearest medical facility that offers PET drugs. A long trip to a medical facility may be beyond the resources or physical capability of many patients. In addition, it is in the interest of public health for FDA not to discourage the development of novel PET agents. Large annual user fee assessments would likely create a disincentive to develop new PET agents.

Second, PET drugs are innovative. Unlike other diagnostic tools, like X-rays and magnetic resonance imaging, which produce images of the body's structure, PET visualizes biochemical events at the cellular level. PET is an extremely sensitive technique that may detect disease before

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20 See FDA, Interim Guidance Document for Waivers of and Reductions in User Fees, at 13 (July 16, 1993).

21 See id. at 13-14.

changes in body structure are evident, such as tumors. In this respect, PET may detect disease at its very beginnings, which can lead to earlier, more specific diagnosis and more effective patient treatment. Because of the unique abilities of PET and PET drugs, the clinical application of PET technology is rapidly growing in use to pinpoint the source of many common cancers, heart disease, and neurological disorders, like Parkinson's disease and Alzheimer's disease.

FDA interprets the second prong under both the "public health" and the "barrier to innovation" waiver mechanisms to involve a specific financial test (i.e., $10 million in annual gross revenues and no corporate parent or funding source with annual gross revenues of $100 million or more).[22] However, the Agency is not statutorily precluded from considering higher annual gross revenue limits. The "public health" exception in the statute does not refer to resources of sponsors at all. Moreover, under the "barrier to innovation" waiver provision, the FDC Act gives the Agency the discretion to consider "other circumstances" aside from "limited resources."[23] The Agency has never articulated a definition of "other circumstances," but FDA could consider the unusual circumstances surrounding the regulatory history and the manufacture and distribution of PET drugs to be the sort of "other circumstances" that would justify a waiver from establishment user fees. Absent a waiver, PET drug manufacturers that supply a national, multistate, or even single-state area would be unfairly penalized for providing a valuable public health service.

b. FDA is Required to Treat Similarly Situated Parties Equitably

In addition to promoting the public health and innovations in PET drug development, the requested waivers would avoid the inequity of assessing commercial PET drug manufacturers

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22 See FDA, Interim Guidance Document for Waivers of and Reductions in User Fees, at 15-17 (July 16, 1993).

> FDA expects to evaluate a person's or entity's request for a fee waiver or reduction under the public health or innovation sections based on the annual revenues of the entity and its affiliates (both domestic and foreign revenues will be evaluated) . . . . [and] expects to grant most of the fee waivers and reductions under the public health and innovation provisions to entities . . . with less than $10 million in annual gross revenues and no corporate parent or funding source with annual gross revenues of $100 million or more.

FDA has not revised this financial test since 1993. New economic factors and annual adjustments would presumably alter the $10/$100 million limit.

23 FDC Act § 736(d)(1)(B).

multiple establishment user fees while assessing manufacturers of other diagnostic and therapeutic drugs a single establishment fee. FDA may not subject two similarly situated parties to divergent treatment.

Section 706(2)(A) of the Administrative Procedure Act ("APA") provides that a court may hold unlawful "agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."[24] Under this "arbitrary and capricious" standard, courts have held that agency action, and particularly FDA action, which treats similarly situated parties in a different manner is a violation of the APA. In Federal Election Comm'n v. Rose, 806 F.2d 1081 (D.C. Cir. 1986), the U.S. Court of Appeals for the District of Columbia stated that, "an agency's unjustifiably disparate treatment of two similarly situated parties works a violation of the arbitrary-and-capricious standard."[25] In Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20 (D.D.C.1997), which concerned FDA's application of different premarket review standards to two similar products regulated by two different centers within FDA, the U.S. District Court for the District of Columbia stated that "[w]hat the FDA is not free to do, however, is to treat [similarly situated parties] dissimilarly and to permit two sets of similar products to run down two separate tracks, one more treacherous than the other."[26]

Once FDA requires the submission of NDAs for PET drugs, PET drug manufacturers will effectively be subject to the same requirements as all other manufacturers of "new drugs" — in all areas except establishment user fees. For example, the establishment fee set for Fiscal Year 2006 is $264,000. A conventional drug sponsor that identifies a single sole-production manufacturing establishment in its "human drug application" will only be assessed an annual $264,000 fee. By contrast, a commercial PET drug manufacturer might identify 10, 20, or more sole-production manufacturing establishments in its marketing application, depending on the sponsor's ability to maximize geographic distribution, and would be assessed $2,664,000, $5,280,000, or more annually for a single NDA product.

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24 5 U.S.C. § 706(2)(A).

25 Rose, 806 F.2d at 1089 (citation omitted).

26 Bracco, 963 F.Supp. at 28 (citation omitted); see also United States v. Diapulse Corp. of Am., 748 F.2d 56, 62 (2d Cir. 1984) (holding that FDA must act "evenhandedly" and may "not 'grant to one person the right to do that which it denies to another similarly situated.'"); Int'l Rehabilitative Sci., Inc. v. Kessler, Civil No. SA-93-CA-0242, 1993, Medical Devices Reports (CCH) ¶ 15,181 (W.D. Tex. June 29, 1993) (finding that FDA's "divergent treatment" of two muscle stimulator devices was "glaring evidence of arbitrary action.").

Large annual assessments would place a significant financial burden on certain PET drug manufacturers, and could eliminate the economies of scale in certain localities, thereby discouraging certain manufacturers from operating PET centers in those localities. Moreover, large annual assessments would likely adversely affect the development of novel PET agents. For example, a PET drug manufacturer within a particular geographic region would have to generate sales profits that exceed the establishment fee costs before there could be any recovery of development costs invested in new product development.

A more equitable and flexible user fee paradigm applicable to PET drugs is needed now for voluntarily submitted marketing applications, and will be even more necessary once FDA requires the submission of marketing applications. In enacting FDAMA § 121, Congress clearly contemplated special class treatment in order not to reduce PET drug availability. FDA's user fee policy should be consistent with this objective. Moreover, a user fee policy that treats all "human drug application" sponsors uniformly is consistent with the Agency's mission to promote and protect the public health. As the court stated in Bracco, "[r]equiring the FDA to [treat products similarly] is consistent with the FDA's mission and is in the public interest."[27]

c. The Creation of a "Class Waiver" for PET Drugs is Supported by Precedent

The concept of administratively creating a "class waiver" from PDUFA user fees is supported by ample precedent. For example, in 2000, FDA determined that the application fee applicable to "human drug applications" for certain PET drugs (i.e., FDG 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection) should be waived, because "assessment of an application fee . . . would present a significant barrier to innovation."[28] More recently, FDA issued a guidance document in April 2005 explaining its policy for waiving PDUFA user fees for certain fixed-dose combination and co-packaged HIV/AIDS drugs proposed for use in the President's Emergency Plan for AIDS Relief ("PEPFAR").[29] Treating PEPFAR products as a class, the

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27 Bracco, 963 F.Supp. at 30.

28 FDA, Notice, Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications, 65 Fed. Reg. 12,999, 13,004 (Mar. 10, 2000). In exchange for the waiver, applicants were required to submit with their application a statement waiving any right to marketing exclusivity. See id. at 13,005.

29 FDA, Guidance for Industry: User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR, Apr. 2005, available at http://www.fda.gov/cder/guidance/6473dft.pdf.

Agency determined that they fully qualify for a "barrier to innovation" user fee waiver, because PEPFAR drugs are innovative and "other circumstances," rather than "limited resources," justify a waiver.[30] Finally, FDA treats certain "combination products" (defined under 21 C.F.R. § 3.2(e)) as a class of products that may be considered "innovative combination products" eligible for a waiver under the "barrier to innovation" waiver mechanism because of "other circumstances."[31]

FDA should consider the circumstances under which PET drugs are manufactured and distributed to be the type of "other circumstances" necessary to justify a "class waiver" from establishment fees under the "barrier to innovation" waiver mechanism, just as the Agency has for other classes of drugs. Alternatively, FDA could justify a "class waiver" from establishment fees under the "public health" waiver mechanism, and adopt a more flexible financial test. A "class waiver" under either mechanism would, in accordance with Congress' instructions in implementing FDAMA § 121, "take account of the special characteristics of [PET] drugs and the special techniques and processes required to produce these drugs" to promote their availability to the patients who need them.[32]

C. Conclusion

For the above reasons, CORAR believes that FDA should waive PET drug establishment fees for all PET drug marketing applications, or require PET drug manufacturers to pay, at most, a single establishment fee. Such a waiver should apply to "human drug applications" submitted following the expiration of the FDAMA § 121 moratorium, as well as to applications voluntarily submitted before that time.

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30 The Agency's guidance document does not describe these "other circumstances" in detail, but instead notes that FDA "intends to consider the development of drugs for the PEPFAR program to be the sort of 'other circumstances' that would justify a waiver of PDUFA user fees under the barrier to innovation waiver provision," provided specific requirements are met. Id. at 4.

31 FDA, Guidance of Industry and FDA Staff: Application User Fees for Combination Products, Apr. 2005, at 7, available at http://www.fda.gov/cber/gdlns/feecomboprod.pdf. In addition to these FDA guidelines permitting PDUFA user fee "class waivers," FDA is currently considering a citizen petition submitted by Orphan Medical, Inc. in January 2003 requesting, in part, "that FDA establish a clear and fair waiver policy from the establishment and product fees for orphan drugs that have modest sales." Orphan Medical, Inc., Citizen Petition, Docket No. 2003P-0039, (Jan. 28, 2003), available at http://www.fda.gov/ohrms/dockets/dailys/03/Jan03/013003/8004bf0a.pdf.

32 FDAMA § 121(c)(1)(A).

III. ENVIRONMENTAL IMPACT

The actions requested in this Petition are not within any of the categories for which an environmental assessment is required pursuant to 21 C.F.R. § 25.22. Additionally, the actions requested in this Petition are exempt from the requirement of an environmental assessment pursuant to 21 C.F.R. § 25.30.

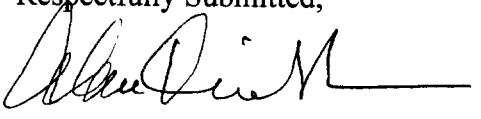
IV. ECONOMIC IMPACT

Information on the economic impact of this proposal can be provided if requested.

V. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes information and views on which the Petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the Petition.

Respectfully Submitted,



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